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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,991	07/26/2001	John Paul McGee	JANS-0008	7988

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,991	MCGEE ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Declaration, Information Disclosure Statement, Power of Attorney, and Preliminary Amendment A, all received by the Office on July 26, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 22 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent 5,213,811 to Frisbee *et al.* in view of US Patent4,663,318 to Davis.

Frisbee *et al.* disclose sugar beads coated with a first coating including a drug and hydroxypropylmethyl cellulose, a second coating including ethylcellulose and a plasticizer, and an additional coating of the drug and hydroxypropyl methyl cellulose. Frisbee *et al.* teach that their compositions provides initial rapid release of the drug, followed by sustained release of the drug as the composition passes through the gastrointestinal tract (c 1, l 63 – c 2, l 31). Additionally, Frisbee *et al.* teach that coated particles can be used to fill a capsule, thereby making a pharmaceutical dosage form (c 2, l 32-34). Frisbee *et al.* further teach that the active agent can be any drug with a solubility of at least 5% by weight in gastric fluid and less than 1% by weight in intestinal fluid.

Frisbee *et al.* does not specifically teach the inclusion of galanthamine in their disclosure. However, although the reference only exemplifies one active agent, they teach that the composition can be used and applied to many other active agents. It is the position of the examiner that when a new formulation or dosage form is discovered it is readily applied to different types of active ingredients. It would be burdensome for the inventor of the new type of dosage form to disclose examples regarding each and every potentially useful active agent. Additionally, looking to the known art for galanthamine, there are no specific guidelines as to how to prepare a dosage form of the drug. For example, Davis teaches galanthamine for the treatment of Alzheimer's disease. In his disclosure, Davis teaches that galanthamine can be administered through solid oral formulations, such as tablets and capsules. Davis further teaches that the tablets and capsules should be prepared by known tablet and capsulemaking techniques (c 2, l 20-44). Therefore, it is the position of the examiner that one of ordinary skill in the art would look to the art regarding pharmaceutical dosage forms to determine an appropriate dosage form for the administration of galanthamine. It is the position of the examiner that Frisbee is one of these such disclosures. Lastly, the burden is shifted to applicant to provide evidence as to why galantamine would not be obvious to use in the dosage form of Frisbee *et al.* If there are chemical or practical reasons making the above combination unobvious, applicant is invited to provide evidence to support this.

Frisbee *et al.* do not disclose applicant's specific plasticizers to be used in combination with ethylcellulose. Frisbee *et al.* teach the use of diacetylated monoglycerides and triacetin. However, in other areas of their disclosure, Frisbee *et al.* teach that triethyl citrate and diethyl phthalate are also acceptable plasticizers. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to use triethyl citrate or diethyl phthalate along with ethylcellulose for its art intended purpose. The selected of a known material based on its suability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Claims 23-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Frisbee *et al.*, in view of Davis, as discussed above, and further in view of WO 98/22072 to Willson.

Frisbee *et al.* in view of Davis are discussed above as teaching a novel dosage form, comprising multicoated particles, wherein it would be obvious to use galanthamine as the active agent. Davis also teaches that it is known to administer tablets of capsule containing 5, 10, and 25 mg of galanthamine hydrobromide to be taken four times a day, or a sustained release preparation delivering an equivalent daily dose.

Frisbee *et al.* in view of Davis. fail to teach a pharmaceutical package comprising a container, a formulation and written matter.

Willson is relied for the teaching that individually separated dosage form packaging is known in the art. Willson discloses a pharmaceutical package for aiding or increasing patient compliance for the administration of a pharmaceutical drug regimen, comprising at least one blister card, wherein each blister card comprises the total daily dose of the pharmaceutical, and wherein each dose section comprises an indicia denoting the time in which the dose is to be administered, as well as a patient information booklet

comprising dosing information, side effect information, and patient incentive information (abstract).

Additionally, due to the teachings of Davis, which teaches administration of a particular amount of active daily, it would have been obvious to one of ordinary skill in the art to package the dosage forms in a system such as that described by Willson. The motivation lies in the teachings and advantages of the Willson system. Additionally, galathamine is used for the treatment of Alzheimer's, where reminders, and additional help in the administration of an active agent would be enormously helpful. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600